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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,891	02/02/2001	William Delaney IV	13381	8348

7590 07/29/2004

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EXAMINER	
GUZO, DAVID	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/781,891	DELANEY ET AL.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2003 and 09 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12,14,15 and 20-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12,14,15 and 20-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: In original Claim 20, applicants recite HBV variants or recombinants or derivatives or components thereof and **chemical equivalents** thereof. The specification does not provide support for the terminology of **chemical equivalents** of the recited HBV variants, recombinants or components thereof.

Sequence Listing

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because nucleotide sequences present in Figures 3, 5 and 14 are not identified by SEQ ID NO identifiers. Also, an amino acid sequence on p. 2, line 5 of the specification is not identified by SEQ ID NO or portion of SEQ ID NO. The Sequence Listing filed 12/4/03 has been received; however, the application does not comply with the Sequence Rules for the reasons cited above.

35 USC 112, 1st Paragraph Rejection (New Matter)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 12, 14-15 and 20-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have amended Claims 1, 23 and 24 to recite a method for detecting a variant HBV or a method for detecting HBV DNA polymerase activity wherein the methods recite generation of a genetic construct comprising a replication competent amount of the genome of a variant HBV contained in or fused to an amount of a baculovirus genome capable of infecting cells **of hepatic origin**. The specification does not provide support for the limitation of infecting cells **of hepatic origin**. The specification provides support for infecting the cell line HepG2, Huh-7 and any hepatocyte cell line or primary hepatocyte cell culture. The limitation of "cells of hepatic origin" is broader than what the specification supports since cells of hepatic origin can encompass cell types of hepatic origin (i.e. oval cells, sinusoidal epithelial cells, hepatic stem cells, etc.) in addition to the hepatocyte cells contemplated by applicants. This is a NEW MATTER rejection.

35 USC 102 Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Locarnini et al.

Applicants claim an HBV variant or a recombinant or derivative form thereof or a chemical equivalent thereof or a recombinant or chemical equivalent of a component thereof detected by the method according to claim 8. The claim therefore reads on any HBV variant comprising an altered DNA polymerase, an altered HBV precore promoter or basal core promoter, an altered HbsAg or a combination thereof wherein said variant HBV exhibits altered sensitivity to an agent as well as a recombinant or chemical equivalent of a component thereof.

Locarnini et al. (Hepatology, Vol. 27, 1998, pp. 294-297, see whole article, particularly p. 294, Table 1 and p. 295, left column) recites well known and characterized HBV variants comprising altered DNA polymerases or HbsAg components wherein said variants exhibit altered sensitivities to agents such as famciclovir and lamivudine. Locarnini et al. therefore teaches the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 20 is rejected under 35 U.S.C. 102(a) as being anticipated by Oon et al.

Applicants' invention is as disclosed in the above 35 USC 102(b) rejection.

Oon et al. (Antiviral Research, 1999, Vol. 41, pp. 113-118, see whole article, particularly the Abstract, Table 1 and the Discussion section) recites HBV variants comprising altered DNA polymerases or HbsAg components wherein said variants exhibit altered sensitivities to agents such as lamivudine. Oon et al. therefore teaches the claimed invention.

35 USC 112, 1st Paragraph (Written Description)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim reads on a genus of HBV variants (recombinant or non-recombinant) or derivatives or chemical equivalents thereof or a recombinant or chemical equivalent of a component thereof detected by the method of claim 8. Claim 8 recites a method for detecting variant HBVs with altered DNA polymerases, altered HBV precore or basal core promoters, altered HbsAg or combinations thereof, said components having altered sensitivities to an agent of interest. Applicants disclose several HBV variants comprising mutations/alterations in the DNA polymerase, HBV precore and basal core promoters and HbsAg components. The genus includes potentially millions of different, undescribed, HBV variants with mutations in the recited HBV components wherein said variants could be identified by the claimed method. The claim must therefore be considered a reach through claim.

The written description requirement for a genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that applicant was in possession of the claimed invention.

In the instant case, the structures of the HBV variants disclosed by applicants provide no disclosure on the structures of any other HBV variants or components thereof with altered sensitivities to any other agents. Applicants claim the recited HBV variants or recombinants by function only without a

disclosed or art recognized correlation between the structures of the variants or recombinants and their function of having altered sensitivity to a given agent. It must be considered that the structures of each variant or recombinant would vary widely because the nature of the variant or recombinant would be dependent upon the nature of the agent tested. With regard to written description of "chemical equivalents" of components of the recited variant or recombinant HBVs, applicants provide no disclosure of any examples of said chemical equivalents and provide no correlation between the structures of said chemical equivalents and their functions. Given the broad scope of the claimed variants or recombinants or chemical equivalents, given the wide diversity of the variants or recombinants or chemical equivalents claimed and given the lack of a correlation between the structures of the variants or recombinants or equivalents and their structures, it must be considered that the skilled artisan would conclude that applicants disclosed examples represent a representative number of examples sufficient to describe the claimed genus.

35 USC 112, 2nd Paragraph Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 is vague in the recitation of an HBV variant or recombinant or a "derivative form thereof or a chemical equivalent thereof" or a "chemical equivalent" of a component thereof. It is unclear what a "derivative form" or "chemical equivalent" thereof with regard to a HBV variant or recombinant encompasses, i.e. what is a chemical equivalent of a variant HBV particle? With regard to derivative forms of HBV variants, it is unclear what processes were used to generate the derivatives and how closely related to the starting material the derivatives are. The metes and bounds of the claimed subject matter are therefore unclear. Claim 20 also reads on "a recombinant or chemical equivalent of a component thereof"; this is confusing. It is unclear if applicants are claiming a recombinant component or a chemical equivalent of a component of the HBV variant or recombinant?

Claims 21 and 22 are vague in the recitation of co-infecting or superinfecting cells with multiple combinations of **the variant HBV** comprising an altered HBV precore promoter or basal core promoter or an altered HBV HBsAg or an altered HBV DNA polymerase or combinations thereof. It is unclear how the skilled artisan could co-infect or superinfect cells with multiple combinations of a single variant HBV. The claims should recite co-infection or superinfection with combinations of **different** variant HBVs. Also, claim 21 is vague in the recitation of the phrase "multiple combinations of the variant HBV **comprises** (emphasis added)"; in this case "comprises" should agree with "combinations" and should be "comprising".

Claim 23 is vague in that applicants recite a method for detecting a variant HBV comprising a DNA polymerase which exhibits altered sensitivity to an agent but the method does not recite a step(s) which would detect said variant with the recited DNA polymerase. The last step in the claim recites performing a DNA polymerase assay in the presence or absence of various analogues, but applicants present no step(s) whereby the results of the assay are interpreted to detect a variant HBV DNA polymerase with altered sensitivity to the test agent. The claim also recites the optional step of further infecting the cells with another construct comprising another HBV variant or wild type HBV but no step in the claim recites how one would distinguish between the DNA polymerase produced by the variant and the wild type HBV or the additional HBV variant introduced in the cells and how one would determine whether the polymerase would exhibit an altered sensitivity to an agent.

Claim 24 is vague because in line 11, applicants recite culturing cells for a time and under conditions sufficient for **the HBV** to replicate, express genetic sequences, etc. However, the cells can potentially contain three different HBV genomes, the first HBV strain genome in the context of a baculoviral vector, wild type HBV and another HBV strain and it is unclear what HBV is being referred to by the phrase "the HBV".

Miscellaneous

In Claim 9, HBV is misspelled as "HBB". Correction is required.

In the Specification, applicants have amended the Brief Description of the Drawings on p. 9, by inserting the Brief Description of Figure 14, between the descriptions of Figures 5 and 6. This is confusing. The Figure descriptions should be numbered consecutively.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0767. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
July 15, 2004

DAVID GUZO
PRIMARY EXAMINER